Federal Advisory Committee (FAC) Membership Balance Plan

(1) FEDERAL ADVISORY COMMITTEE NAME

State the legal name of the FAC

Blood Products Advisory Committee

(2) AUTHORITY

Identify the authority for establishing the FAC

The Blood Products Advisory Committee was established under 15 U.S.C. 1451 et seq.; 21 U.S.C. 321, 341, 342, 343, 343-1, 344, 345, 346, 348, 349, 350, 350a, 351, 352, 353(f), 355, 360b, 360c-j, 371, 375, 376, 378, 379e, 381, 393, 394, 881(b); 42 U.S.C. 217a, 241, 242, 242a, 262, 264; 21 CFR Part 14, 330.10(a); Pub. L. 92-463 (5 U.S.C. App.), the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees.

(3) MISSION/FUNCTION

Describe the mission/function of the FAC

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and advises the Commissioner of Food and Drugs of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

(4) POINTS OF VIEW

Based on understanding the purpose of the FAC,
(a) describe the process that will be used to ensure the committee is balanced, and identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered;
(b) consider identifying an anticipated relative distribution of candidates across the categories; and
(c) explain how a determination was made to appoint any individuals as Special Government Employees or Representative members

The Blood Products Advisory Committee consists of a core of 17 voting members including the Chair. Specific expertise relevant to the mission/function of the committee includes: among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions.

The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Where defined by committee charter, the Commissioner or designee shall have the authority to select members of other FDA advisory committees to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when expertise is required that is not available among current voting standing members or to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

A review of a potential member's curriculum vitae, conflict of interest forms, list of publications and committee affiliations is conducted to determine points of view and committee balance. The charter is renewed every two years to determine needed expertise based on upcoming and projected committee topics. It is expected that balance is not static, and the expertise or experience relevant to the mission/function of this committee may change over time, depending on the work of the committee.

Generally, members are designated as Regular Government Employees or Special Government Employees. Industry and Consumer representative members on the committee are identified by either a consortium of consumer-oriented organizations or industry organizations.

(5) OTHER BALANCE FACTORS

List any other factors your agency identifies as important in achieving a balanced FAC

Appointments shall be made without discrimination on the basis of age, race, gender, sexual orientation, HIV status, and cultural, religious, or socioeconomic status. During the nomination process, the committee is reviewed in totality for balance with regard to geographic location and female and minority representation. A balanced committee is characterized by inclusion of the necessary knowledge, insight, and scientific perspective from the community or expertise area which the members serve.

(6) CANDIDATE IDENTIFICATION PROCESS

Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance. The summary should:

(a) describe the process
(b) identify the agency key staff involved (by position, not name)
(c) briefly describe how FAC vacancies, if any, will be handled by the agency; and
(d) state the membership term limit of FAC members, if applicable

FDA staff involved in advisory committee activities are responsible for recruiting members to fill vacancies. A Federal Register Notice announcement is published soliciting nominations for vacancies in the coming year. Agency Designated Federal Officers and Office/Division Directors are responsible for the initial review and evaluation of prospective members for competence and membership suitability. All individuals interested in serving as members should have the background, education, and experience commensurate with function of the committee and the advice it renders. Scientific and technical competence is critical. Special attention is also paid to leadership qualities. Whenever possible, nominees are acknowledged experts in their fields whose credibility is beyond question. All nominees should have demonstrated skills in critical evaluation of data and communication skills necessary to promote efficient and effective deliberation.

Membership structure is outlined in the committee charter that describes the desired scientific expertise as well as needed individuals with consumer and industry interests.

The responsible office seeks qualified candidates from relevant professional, scientific, and medical societies, medical and other professional schools, academia, government agencies, industry and trade associations, consumer and patient organizations, and professional organizations likely to have knowledge of women and minority candidates. Consideration is given to the use of vacancy announcements in nationally recognized medical and scientific journals. Nominations are also sought from appropriate staff within the Agency as well as from current and former members. A computerized database established by the Agency is also utilized to identify potential committee members.

Designated Federal Officers, Division/Office Directors, and the Advisory Committee Oversight and Management Staff work to see that committees are balanced. Nominations are to be requested from all geographic locations within the United States or its territories. Anyone may nominate an individual, including them self, for committee membership.

The responsible office must keep abreast of term ending dates and have appointments to fill vacancies ready in advance. Approximately nine to twelve months before a vacancy is to occur, the Designated Federal Officer works with appropriate officials to discuss candidates and mechanisms to seek additional nominations. The Designated Federal Officer is responsible for ensuring that vacancies are filled promptly, terms remain staggered as provided in the committee charter, and, to the extent possible, full slates of nominees are submitted for vacancies.

Members will be invited to serve for overlapping terms of up to four years. If appointed to fill an unexpected vacancy due to retirement or otherwise, the newly appointed member is to serve only the remainder of the four-year term. Term stratification exists with the goal to avoid no more than 33% of members rotating off the committee at one time. This limits frequent turnover, maintains expertise and experience, and brings new perspectives to the committee.

The Commissioner or designee makes the final decision about who will serve on the committee.

(7) SUBCOMMITTEE BALANCE

Subcommittees subject to FACA should either state that the process for determining FAC member balance on subcommittees is the same as the process for the parent FAC, or describe how it is different*
**This is relevant to those agencies that require their subcommittees to follow all FACA requirements.*

N/A

(8) OTHER

Provide any additional information that supports the balance of the FAC

The advisory committee system enables the FDA to secure the professional expertise and vital support necessary to accomplish its mission and maintain public trust. The committees consist of individuals possessing recognized expertise and judgment in specific fields. Members have the training and experience necessary to evaluate information objectively and to interpret its significance under various, often controversial, circumstances.

All standing members, with the exception of Industry Representatives, are appointed as Regular Government Employees or Special Government Employees. Regular Government Employees and Special Government Employees are subject to the federal financial conflict of interest requirements as required by the Ethics in Government Act of 1978.

Industry Representative members are expected to represent the views of relevant stakeholders with an interest in the subject of discussion, such as an industry, a union, an environmental organization, or other such entity. Industry Representatives are expected to represent a particular and known bias and it is understood that information, opinions, and advice from these representatives reflects the particular group they are appointed to represent. Because these individuals are to represent outside interests, they do not meet the statutory definition of a Regular Government Employee or Special Government Employee and are therefore not subject to the criminal financial conflict of interest statute.

Consumer Representatives also are expected to represent the views of relevant stakeholders with an interest in the subject of discussion. However, due to the various possible consumer interests, the Agency has decided to appoint these individuals as Special Government Employees, subject to the Federal financial conflict of interest requirements.

(9) DATE PREPARED/UPDATED

Insert the actual date the Membership Balance Plan was initially prepared, along with the date(s) the Plan is updated

Bryan Emery, R.N., LCDR, USPHS, DFO — **03/18/2016** **Date**